IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

THEORY NIENOW
1798 Hwy. 175
Richfield, WI 53076,

Plaintiff,

Case No. _____

vs.

STRYKER CORPORATION,
a Michigan corporation,
c/o CT Corporation System, Registered Agent
8040 Excelsior Drive, Suite 200
Madison, WI 53717,

COMPLAINT AND DEMAND FOR JURY TRIAL

and

STRYKER SALES CORPORATION,
a Michigan corporation,
c/o CT Corporation System, Registered Agent
8040 Excelsior Drive, Suite 200
Madison, WI 53717,

Defendants.

NOW COMES the above-named plaintiff, Theory Nienow, by her attorneys, Provost Umphrey Law Firm, LLP and Laufenberg, Stombaugh & Jassak, S.C., and for her Complaint against the above-named defendants, alleges and shows to the court as follows:

PARTIES

1. The plaintiff, Theory Nienow, is an adult citizen and resident of the State of Wisconsin, and resides at 1798 Hwy. 175, Richfield, Wisconsin 53076. Theory Nienow was implanted with a "pain pump" that was manufactured and/or placed into the stream of commerce by the Defendants, Stryker Corporation and/or Stryker Sales Corporation.

2. The defendant, Stryker Corporation (hereinafter, "Stryker"), is a Michigan corporation, with its principal place of business located at 2825 Airview Blvd., Kalamazoo, MI 49002, and the offices of its Registered Agent, CT Corporation System, located at 8040 Excelsior Drive, Suite 200, Madison, WI 53717. At all times material hereto, Stryker Corporation was authorized to, and did conduct substantial, regular and sustained, business in the State of Wisconsin and was engaged in the business of designing, manufacturing, distributing and selling "pain pumps" in the State of Wisconsin.

3. The defendant, Stryker Sales Corporation (hereinafter, "Stryker Sales"), is a Michigan corporation, with its principal place of business located at 2825 Airview Blvd., Kalamazoo, MI 49002, and the offices of its Registered Agent, CT Corporation System, located at 8040 Excelsior Drive, Suite 200, Madison, WI 53717. At all times material hereto, Stryker Sales Corporation was authorized to, and did conduct substantial, regular and sustained, business in the State of Wisconsin and was engaged in the business of designing, manufacturing, distributing and selling "pain pumps" in the State of Wisconsin.

JURISDICTION AND VENUE

4. The court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a)(1), because the parties are citizens of different states, and the amount in controversy between the parties exceeds the sum of $75,000.00, exclusive of interest and costs.

5. This court has personal jurisdiction over the defendants, Stryker and Stryker Sales, because, at all times material hereto, they transacted business in the State of Wisconsin, and the wrongs complained of arose in the State of Wisconsin.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391, because a substantial part of the events giving rise to the plaintiff's claims occurred in this district, and because the defendants transact business in this district.

FACTUAL BACKGROUND

7. On March 9, 2005, the plaintiff, Theory Nienow, underwent arthroscopic surgery on her left shoulder at Oconomowoc Memorial Hospital in Oconomowoc, Wisconsin. The surgery was performed by Gerard Adler, MD. Following surgery, Dr. Adler affixed a "pain pump," specifically identified by the plaintiff as a product of the defendants, Stryker and/or Stryker Sales, to the plaintiff's shoulder with a continuously injected anesthetic. That "pain pump," through a catheter emanating from the pump and implanted through the skin and into her shoulder joint, injected anesthetic on a continuous basis following the plaintiff's surgery.

8. While it is not possible to pinpoint the exact moment the pain pump began injuring the plaintiff, in all likelihood the injury began on or shortly after the administration of anesthetics via the post-operative pain pump following her surgery on March 9, 2005.

9. The defendants, Stryker and Stryker Sales, design, manufacture, distribute and sell a product called a "pain pump," which is a medical device intended to deliver, via catheter, continuous doses of pain relief medication directly into the shoulder joint space. The pain pump delivers anesthetic pain medication directly into the operative site for 48 hours or more immediately following shoulder surgery.

10. The pain pump is designed and intended for use with common anesthetics such as lidocaine and/or marcaine, with or without epinephrine, over two days or more. The continuous injection of such medications over time directly into the shoulder joint, however, causes serious and permanent damage to the cartilage of the shoulder joint. The result is a narrowing of the joint space

and/or a condition called "chondrolysis." Chondrolysis is the complete or nearly complete loss of cartilage in the shoulder joint. It is an irreversible, disabling, and extremely painful condition.

11. The plaintiff, Theory Nienow, had one of the defendants', Stryker and Stryker Sales, pain pumps inserted following a shoulder surgery on March 9, 2005. The pain pump delivered dangerous doses of medication continuously injected in the shoulder joint. As a result, the plaintiff, Theory Nienow, suffered loss of cartilage and chondrolysis.

12. The plaintiff, Theory Nienow, has either already undergone, or will require, additional surgery, including complete shoulder joint replacement or joint fusion, as a result of the narrowing of the joint space and/or chondrolysis caused by the defendants', Stryker and Stryker Sales, dangerously defective pain pump.

13. The defendants, Stryker and Stryker Sales, did not warn Theory Nienow or her surgeon about the unreasonable risks and dangers of using the pain pump in this manner.

14. The defendants', Stryker and Stryker Sales, instructions and warnings were inadequate in that the foreseeable risk of harm to Theory Nienow's shoulder posed by the pain pump could have been reduced or avoided by the provision of reasonable instructions or warnings by Stryker and Stryker Sales, and the omission of the instructions or warnings rendered the pain pump not reasonably safe.

15. The above described defective condition of the pain pump rendered it unreasonably dangerous to persons, including Theory Nienow, and the pain pump was in the above described defective condition when it left the control of the defendants, Stryker and Stryker Sales, and remained in that condition up to and including the time Theory Nienow's surgeon used the pain pump, without material or substantial change in its condition and in a foreseeable and intended manner and as instructed and directed by the defendants, Stryker and Stryker Sales.

16. The defective and unreasonably dangerous condition of the defendants', Stryker and Stryker Sales, pain pump was a cause of plaintiff's injuries and damages.

DISCOVERY RULE

17. Despite the exercise of reasonable care and diligence, the plaintiff, Theory Nienow, did not discover that her injuries may have been caused by the defendants', Stryker and Stryker Sales, conduct and/or the defective and unreasonably dangerous condition of the defendants', Stryker and Stryker Sales, pain pump, until a date less than three years from the filing of the Original Complaint in this case. Exercise of reasonable care and/or diligence would not have resulted in the discovery the link between the plaintiff's, Theory Nienow, injury and defendants', Stryker and Stryker Sales conduct and/or the defective and unreasonably dangerous condition of the defendants', Stryker and Stryker Sales, pain pump before that time.

FRAUDULENT CONCEALMENT

18. Any applicable limitations statutes have been tolled by the knowing and active concealment and denial of material facts known by Stryker and Stryker Sales when they had a duty to disclose those facts. Stryker and Stryker Sales have kept the plaintiff, Theory Nienow, ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on the part of the plaintiff, Theory Nienow, for the purpose of obtaining delay on the plaintiff's part in filing a complaint on these causes of action. The fraudulent concealment of Stryker and Stryker Sales did result in such delay.

19. The defendants, Stryker and Stryker Sales, engaged in the following conduct, among other things, which was intended to and did conceal material facts:

a. Stryker and Stryker Sales knew that the FDA had repeatedly refused to allow an indication for use of their pain pumps in the joint space, but Stryker and Stryker Sales failed to disclose that information to doctors and patients;

b. Stryker and Stryker Sales failed to disclose that they had failed to undertake the necessary research, analysis and testing to determine the safety of the use of their pain pumps in the joint space, despite knowing that the pumps would be used in that way;

c. Stryker and Stryker Sales failed to disclose to the U.S. medical community that the use of pain pumps in the joint space was an "off label" use, not approved by the FDA;

d. Stryker and Stryker Sales failed to properly investigate and report to the FDA once they began receiving reports of dozens of patients who had allegedly suffered injury to their cartilage following use of pain pumps in their shoulder joints.

e. Stryker and Stryker Sales failed to disclose that the FDA had repeatedly rejected their proposed indication for use in the joint space – even to their own sales force;

f. Stryker and Stryker Sales failed to adequately disclose the risk of serious and permanent injury to cartilage associated with the use of pain pumps in the joint space for a prolonged period of time after Stryker and Stryker Sales became aware of the risk; and

g. Stryker and Stryker Sales are, and were, under a continuing duty to disclose the true character, danger, and nature of their medical devices, but instead Stryker and Stryker Sales concealed them.

20. The failure of Stryker and Stryker Sales to meet their legally required duty under 21 CFR 803 to inform the FDA about reports of cartilage damage related to use of their pain pumps in the joint space favors equitable tolling of the statute of limitations.

FIRST CAUSE OF ACTION: STRICT LIABILITY

21. The plaintiff incorporates the allegations set forth in Paragraphs 1 through 20, above, as if fully set forth herein.

22. The defendants, Stryker and Stryker Sales, are or were engaged in the business of selling, manufacturing, producing, designing and/or otherwise putting into the stream of commerce "pain pumps". These pain pumps reached the ultimate user, including Theory Nienow, without

substantial change in the condition in which they were sold, manufactured, produced, designed and/or otherwise put into the stream of commerce.

23. The defendants, Stryker and/or Stryker Sales, contractually assumed one of the manufacturer's duties to manufacture, design, or provide warnings or instructions with respect to the subject pain pump.

24. The subject pain pump was in an unreasonably and dangerously defective condition, beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the device, in one or more of the following particulars:

a. The labeling failed to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the intra-articular joint space of the shoulder;

b. The labeling failed to disclose to the U.S. medical community that continuous injection of commonly used anesthetics, such as lidocaine or marcaine with or without epinephrine, in high volumes, over two days or more, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

c. The labeling failed to include a precaution against placing the catheter of the pain pump directly in the shoulder joint space;

d. The labeling failed to provide to the U.S. medical community adequate instructions for the safe use of the device, failing specifically to identify quantities, flow rates, and types of anesthetic medications that could be safely and effectively used in the shoulder joint space;

e. The labeling failed to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use directly in the shoulder joint space;

f. The labeling failed to disclose to the U.S. medical community that the Food & Drug Administration (hereinafter "FDA") had considered requests to add use of the pain pump in a joint space as an indication for use in pain pump labels, but would not clear the addition of this use of pain pumps;

g. The pain pump was designed to inject foreseeable and commonly used medications associated with damage to articular cartilage directly into the shoulder joint; and

h. When used as designed, the pain pump delivered, over time, dangerously high doses of pain medications directly into shoulder joints.

25. The product defects and unreasonably dangerous conditions alleged above were foreseeable and were a cause of the injuries and damages sustained by the plaintiff, Theory Nienow. Specifically, the pain pump legally caused Theory Nienow to suffer the permanent loss of cartilage in the shoulder, resulting in past and future pain and suffering, past and future mental anguish, past and future medical expenses, past and future disfigurement, past and future physical impairment, and past and future loss of earning capacity.

SECOND CAUSE OF ACTION: NEGLIGENCE

26. The plaintiff incorporates the allegations set forth in Paragraphs 1 through 25, above, as if fully set forth herein.

27. At all relevant times, the defendants, Stryker and Stryker Sales, knew or reasonably should have known, that the pain pump was unreasonably dangerous and defective when used as directed and as designed. A reasonably careful search and review of the scientific and medical literature, and other information, should have indicated to the defendants, Stryker and Stryker Sales, that, among other things:

a. Commonly used anesthetics likely to be used in their pain pump, such as lidocaine and marcaine with or without epinephrine, were harmful to human and animal articular cartilage;

b. Use of the pain pump in a joint space had not been cleared by the FDA and, in fact, had been specifically rejected by the FDA;

c. Continuous injection of high volumes of such medications, through a catheter, directly into the shoulder joint, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of chondrolysis and other serious post-operative problems associated with using the pain pump as designed and instructed outweighed the possible benefits of such use.

28. Based on what the defendants, Stryker and Stryker Sales, knew or reasonably should have known, the defendants, Stryker and Stryker Sales, were negligent in one or more of the following ways, among others:

a. In failing to instruct or warn the U.S. medical community and public, including Theory Nienow, that the safety of the pain pump device had not been established for use in the shoulder joint space;

b. In failing to disclose to the U.S. medical community and public, including Theory Nienow, that continuous injection of commonly used anesthetics, such as lidocaine or marcaine with or without epinephrine, in high volumes, over two days or more, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

c. In failing to include a precaution against placing the catheter of the pain pump directly in the shoulder joint space;

d. In failing to provide to the U.S. medical community and public, including Theory Nienow, adequate instructions for the safe use of the device, specifically failing to identify quantities, flow rates, and types of anesthetic medications that could be safely and effectively used in the shoulder joint space;

e. In failing to disclose the U.S. medical community and public, including Theory Nienow, that the effectiveness of the device was uncertain for use directly in the shoulder joint space;

f. In failing to disclose to the U.S. medical community and public, including Theory Nienow, that the FDA had considered requests to add use of the pain pump in a joint space as an indication for use in pain pump labels, but would not clear the addition of this use of pain pumps;

g. Designing and manufacturing a product designed to deliver, over time, dangerously high doses of pain medications directly into shoulder joints; and promoting and marketing the pain pump for use in the joint space after the FDA had considered and rejected such an indication for use.

29. The plaintiff, Theory Nienow, was unaware of the hazards and defects in the product of the defendants, Stryker and Stryker Sales, which made the pain pump defective and unreasonably dangerous.

30. During the periods that Theory Nienow was using the pain pump of the defendants,

Stryker and Stryker Sales, it was being used in a manner which was intended by the defendants, Stryker and Stryker Sales.

31. The negligent acts and omissions alleged above were foreseeable and proximate causes of the injuries and damages sustained by the plaintiff, Theory Nienow. Specifically, the negligent acts and omissions legally caused Theory Nienow to suffer the permanent loss of cartilage in the shoulder, resulting in past and future pain and suffering, past and future mental anguish, past and future medical expenses, past and future disfigurement, past and future physical impairment, and past and future loss of earning capacity.

THIRD CAUSE OF ACTION: BREACH OF WARRANTY

32. The plaintiff incorporates the allegations set forth in Paragraphs 1 through 31, above, as if fully set forth herein.

33. By intentionally promoting and knowingly selling the pain pump for use in infusing dangerous medication into the intra-articular space of the shoulder following surgery, the defendants, Stryker and Stryker Sales, impliedly warranted to the plaintiff, Theory Nienow, that it was merchantable, that it was proven safe and effective for use, that it was properly labeled, and that it contained proper instructions for its intended use.

34. That implied warranty extended to the plaintiff, Theory Nienow, as the ultimate consumer and user of the pain pump.

35. The defendants, Stryker and Stryker Sales, breached their implied warranty to the plaintiff in that, among other things, the pain pump was unmerchantable, and was not safe for use in infusing the medications into the intra-articular space of the shoulder following surgery.

36. The defendants', Stryker and Stryker Sales, breach of implied warranty was a foreseeable and proximate cause of the injuries and damages sustained by the plaintiff, Theory

Nienow. Specifically, Theory Nienow suffered the permanent loss of cartilage in the shoulder, resulting in past and future pain and suffering, past and future mental anguish, past and future medical expenses, past and future disfigurement, past and future physical impairment, and past and future loss of earning capacity.

FOURTH CAUSE OF ACTION: PUNITIVE DAMAGES

37. The plaintiff incorporates the allegations set forth in Paragraphs 1 through 36, above, as if fully set forth herein.

38. The actions and inactions of the defendants, Stryker and Stryker Sales, as specifically alleged herein above, whether taken separately or together, constituted malicious acts toward the plaintiff, Theory Nienow, and/or constituted an intentional disregard of the rights of the plaintiff, Theory Nienow.

39. The actions and inactions of the defendants, Stryker and Stryker Sales, as specifically alleged herein above, whether taken separately or together, were of such a character as to constitute a pattern or practice of intentional wrongful conduct and/or malice resulting in damages and injuries of the plaintiff, Theory Nienow. The conduct of the defendants, Stryker and Stryker Sales, was specifically intended by Stryker and Stryker Sales to cause substantial injury to Theory Nienow, or was carried out by Stryker and Stryker Sales with a flagrant disregard for the rights of others and the actual awareness on the part of Stryker and Stryker Sales that the conduct would, in reasonable probability, result in human death and/or great bodily harm. More specifically, Stryker and Stryker Sales consciously and/or deliberately engaged in oppression, fraud, willfulness, wantonness and/or malice with regard to Theory Nienow, and should be held liable in punitive and exemplary damages to the plaintiff, Theory Nienow.

WHEREFORE, the plaintiff, Theory Nienow, demands judgment of and from the Defendants, jointly and severally, as follows:

1. In favor of the plaintiff, Theory Nienow, for compensatory damages in an amount to be determined by a jury.

2. In favor of the plaintiff, Theory Nienow, for punitive and exemplary damages in an amount to be determined by the jury.

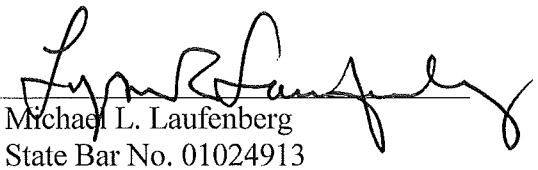
3. In favor of the plaintiff, Theory Nienow, for all costs, disbursements and interest as permitted by law.

4. For such other further legal and equitable relief as may be required or justified.

PLEASE TAKE NOTICE THAT THE PLAINTIFF HEREBY DEMANDS TRIAL BY A JURY IN THE ABOVE MATTER.

Respectfully Submitted,

Dated: 05/01/2012

By: 

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